



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 2, 2016

Ingen Orthopedics, LLC
Mr. Perry A. Geremakis
President, Chief Executive Officer
2650 U.S. Highway 130
Cranbury, New Jersey 08512

Re: K120374

Trade/Device Name: SEVIIN Reverse Shoulder
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX
Dated: June 29, 2012
Received: July 3, 2012

Dear Mr. Geremakis:

This letter corrects our substantially equivalent letter of July 9, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K120374

Device Name: SEVIIN Reverse Shoulder

Indications for Use:

The SEVIIN Reverse Shoulder is indicated for primary, fracture or revision total shoulder arthroplasty for the relief of pain and to improve function in patients with a massive and non-repairable rotator cuff tear.

The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The humeral component is intended for cemented use and the TPS coated metaglene component is intended for cementless use with the addition of screws for fixation.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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510(k) Summary

Prepared: February 4, 2012

Submitter: Ingen Orthopedics, LLC
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Contact: Perry A. Geremakis
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Proprietary Name: SEVIIN Reverse Shoulder

Common Name: Total Shoulder Prosthesis

Classification Names: 21 CFR 888.3660: Shoulder joint metal/polymer semi-constrained cemented prosthesis; Class II

Product Codes: KWS

**Substantially
Equivalent Devices:** Zimmer Anatomical Shoulder Inverse/Reverse Total
Shoulder Prosthesis, K053274, cleared January 25, 2006

Tornier Aequalis Reversed Shoulder Prosthesis, K041873,
cleared August 25, 2004

Encore Medical Encore Reverse Shoulder Prosthesis,
K041066, cleared March 24, 2005

Genesis Medical Genesis Total Shoulder Replacement,
K043346, cleared January 31, 2005

Device Description:

The SEVIIN Reverse Shoulder is a total shoulder prosthesis designed for use in patients with non-functional rotator cuffs. The articulation of this design is "inverted" compared to traditional total shoulder prostheses. The reverse shoulder is designed so that the "ball" of the articulation is on the glenoid side and the mating "cup" fits into the humeral stem. The

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components of the system include a Ti-6Al-4V alloy metaglene plate with titanium plasma spray coating, Ti-6Al-4V alloy bone screws, a Co-Cr-Mo alloy glenosphere, a Co-Cr-Mo alloy humeral cup and an ultra high molecular weight polyethylene (UHMWPE) inlay. These components are intended for use with the previously cleared SEVIIN humeral stems (cleared as the Genesis humeral stems).

The metaglene plate incorporates a cannulated cancellous central screw with cross holes and 4 peripheral screws for added stability. The screws have a 4.5mm diameter and are available in lengths of 24mm, 33mm and 42mm. The glenosphere mates with the metaglene plate via a taper lock and a glenosphere screw. The glenosphere is available in 36 and 40 mm diameter sizes with standard and +4 mm offsets.

The humeral cup mates with the humeral stem via a taper lock. The humeral cup is available in standard and +9 mm offsets. The proximal side of the humeral cup incorporates a snap-fit mechanism and anti-rotation tabs that mate with the poly inlay. The poly inlay is a concave liner that is intended to articulate with the glenosphere proximally and attach to the humeral cup distally. The poly inlay is available in 36 mm and 40 mm diameters, centered and retentive, with 0, +3, and 6 mm offsets.

Intended Use / Indications:

The SEVIIN Reverse Shoulder is indicated for primary, fracture or revision total shoulder arthroplasty for the relief of pain and to improve function in patients with a massive and non-repairable rotator cuff tear.

The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The humeral component is intended for cemented use and the TPS coated metaglene component is intended for cementless use with the addition of screws for fixation.

Summary of Technologies/Substantial Equivalence:

The SEVIIN Reverse Shoulder is substantially equivalent to the predicate devices in regards to its intended use and indications, materials, size ranges, and design intent. Any noted differences do not raise new types of safety and effectiveness questions, nor are there new technological issues.

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Non-Clinical Testing:

Analysis of Range of Motion and testing of glenoid component fixation, assembly fatigue, humeral cup and poly inlay fixation and medical bone screw properties indicate that all components are adequate for their intended use.

Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence of the SEVIIN Reverse Shoulder to the predicate devices.